DEC 16 2005

7.A 510(k) SUMMARY K052840

(As required by Section 807.92(c))

Applicant's Name: Denx Ltd.
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Date Prepared: May 2005

Trade Name: IGI-System™

Classification: The FDA has classified "sterotaxic Instruments" devices as class II, pursuant to 21 C.F.R. § 882.4560 (product code HAW), and it is reviewed by the General & Plastic Surgery Advisory Committee.

Predicate Devices: IGI- Image Guided Implantology System cleared under (K)023424

Description of the Device: System enabling image guided surgery for dental implant surgery through the utilization of planning software based on patient CT, registration through the use of fiducial markers and real time navigation by tracking both patient and handpiece movement and comparing to the pre-defined surgery plan.

Indications for use: The IGI Image-Guided Implantation system, is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides accurate navigational guidance of surgical instruments, with regard to the pre-operative planning in dental implantation procedure.

The device is intended for use for partially edentulous and edentulous patients who require dental implants as part of their treatment plan.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

DenX Advanced Dental Systems
% Patricia Murphy
Kema Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K052840
Trade/Device Name: IGI-System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: December 7, 2005
Received: December 8, 2005

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. C INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K052840

Device Name: IGI Image Guided Implantion System

Indications for Use:

The IGI-System™, Image-Guided Implantation System, is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides accurate navigational guidance of surgical instruments, with regard to the pre-operative planning in dental implantation procedure.

The device is intended for use for partially edentulous and edentulous patients who require dental implants as part of their treatment plan.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Barbara Bruehl for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052840